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Fax Cover Sheet

Date: 07 Aug 2001

To: Ann Brown	From: Ram R Shukla
Application/Control Number: 09/276,820	Art Unit: 1632
Fax No.: 216-361-9495	Phone No.: (703) 305-1677
Voice No.: 216-426-3586	Return Fax No.: (703) 308-4242
Re:	CC:
<input checked="" type="checkbox"/> Urgent <input checked="" type="checkbox"/> For Review <input type="checkbox"/> For Comment <input type="checkbox"/> For Reply <input type="checkbox"/> Per Your Request	

Comments:

Number of pages 5 including this page

STATEMENT OF CONFIDENTIALITY

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Assistant Commissioner for Patents

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ann Brown on

2. The application has been amended as follows:

IN THE SPECIFICATION:

The abstract has been replaced with the following abstract:

--The field of the invention is activating gene expression or causing over-expression of a gene by recombination methods in situ. The invention relates to expressing an endogenous gene in a cell at levels higher than those normally found in the cell. Expression of the gene is activated or increased following integration, by non-homologous or illegitimate recombination, of a regulatory sequence that activates expression of the gene. The method allows the identification and expression of gene undiscovered by current methods since no target sequence is necessary for integration. Thus, gene products associated with human disease and development are obtainable from gene that have not been sequenced and indeed, whose existence is unknown, as well as from well characterized genes. The methods provide gene products from such genes for therapeutic and diagnostic purposes. In one embodiment the vector comprises a promoter, an exon, and an unpaired splice donor sequence, the exon being derived from a eukaryotic gene.--

On page, 130, in lines 10 and 11, at the end of the sentence add a ".".

On page, 130, in lines 11, at the end of the sentence add a ".".

On page 134, in line 22, at the end of the sentence add a ".".

On page 140, in line 30, at the end of the sentence add a "."..

On page 140, in line 26, replace the term "he" after the term "add" with the term "the".

IN THE CLAIMS:

Claims 58, 59, 64-69, 71-74, 76-82, 85-93, 96-123, 128, 129, 131, 132, 159, 161, 162, 164-167, 169-175, 177-183, 223-226, and 232-270 have been cancelled.

In claim 271,

Line 1, replace "expression of a gene" with "expression of an endogenous gene".

Line 2, replace "said cell" with "said isolated eukaryotic cell".

Line 7, replace "a eukaryotic target cell" with "said isolated eukaryotic cell".

Line 9, replace said "cellularly encoded gene" with "said endogenous gene".

3. Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Specifically the application fails to comply with CFR 1.821(d), which states:

(d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph © of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

The specification discloses nucleotide and amino acid sequences in figures 14-16 and 29-35. However, these sequences are not identified by sequence identifiers. For compliance with sequence rules, it is necessary to include the sequence in the "Sequence Listing" and identify them with SEQ ID NO. In general, any sequence that is disclosed and/or claimed as a sequence, i.e., as a string of particular bases or amino acids, and that otherwise meets the criteria of 37 CFR 1.821(a), must be set forth in the "Sequence Listing." (see MPEP 2422.03).

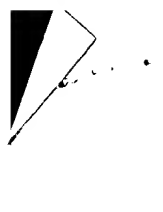
For the response to this office action to be complete, Applicants are required to comply with the Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

4. The following is an examiner's statement of reasons for allowance:

The claimed invention is free of the prior art of record because the prior art of record does not teach or fairly suggest that a method of activating an endogenous gene in an eukaryotic cell by randomly integrating a vector construct wherein the vector construct comprises a promoter operably linked to a eukaryotic exon wherein the 3' end the exon is defined by an unpaired splice donor site. The art of record is US patent 6,080,576, effective filing date 3-27-1998. Claim 15 of the patent recites the same invention as the invention of the instant application.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached on (703) 305-6608. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or



Application/Control Number: 09/276,820

Page 5

Art Unit: 1632

proceeding should be directed to the Kay Pinkney whose telephone number is (703) 305-3553.

Ram R. Shukla, Ph.D.